# CDPH VFC Update April, 2016

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### Disclosure

- Speaker has no financial conflict with manufacturers of any product named in this presentation
- The use of trade names and commercial sources during this presentation is for identification only, and does not imply endorsement by the U.S. Department of Health and Human Services, the U.S. Public Health Service, the Centers for Disease Control and Prevention or the State of California, Immunization Branch.

# VFC PROGRAM- VACCINE SUPPLY UPDATE

Vaccine Management & VFC Program Update

### VFC Flu Vaccine Supply Update,

- VFC Supplemental Flu Ordering:
  - All formulations are available on VFC's Supplemental Ordering
  - Flu season is not over continue administering doses until expiration
  - Remember to administer second doses when appropriate

- Sanofi Pasteur notified CDC about expected manufacturing delays for Pentacel® (DTaP-IPV/Hib combination vaccine)
- Delays are expected from now through the summer of 2016.
- Available supply nationwide is expected to be 70% of the normal supply.

- To ensure that providers have equitable access to Sanofi Pasteur's pertussis-containing vaccines, the VFC Program:
  - All Pentacel orders (and corresponding antigens) be submitted monthly, effective 01/01/2016
  - All Pentacel orders are <u>currently</u> limited to approximately 70% of 2015 average monthly usage (30% reduction)
    - Depending on available vaccine supply, may be adjusted as necessary

- All provider orders will have an order cap in place through the duration of the shortage
- Cap is visible to providers on VFC order form
- Doses of Pentacel reduced by the cap will be added into the single antigen components (ActHib and Daptacel)
- Cap is an allocation per month, therefore providers are allowed to order once per month

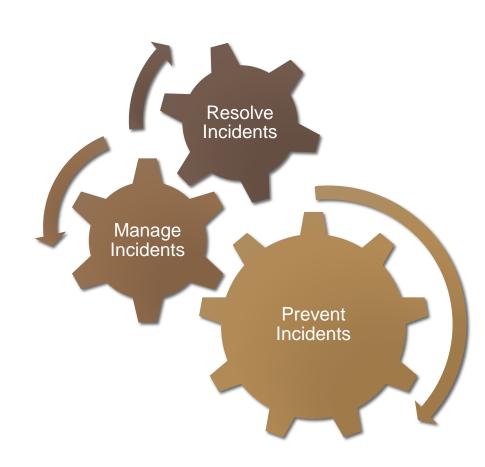
- **Proposed guidance**: Providers should reserve the use of Pentacel® for the administration of the first 3 doses in the primary series, and administer dose 4 as single antigen components.
- ActHib allocation is limited.
- If a provider requests to switch to Pediarix for ALL patients, VFC is requesting that the provider agrees to use PedvaxHib while ActHib limitations are in place.
- Form must be signed by POR or Medical Director acknowledging switch to Pediarix and agreement to also switch to PedvaxHib

### STORAGE AND HANDLING

Vaccine Management & VFC Program Update

### What's new in 2016

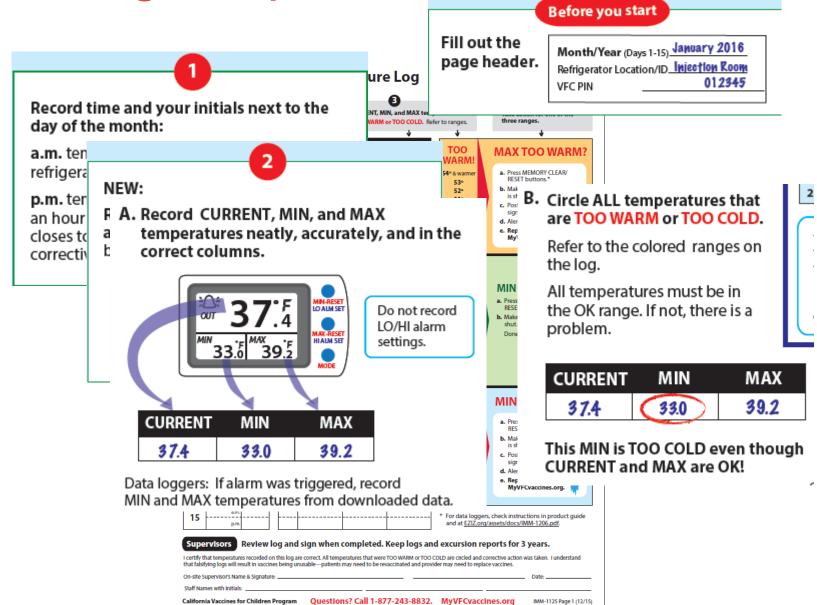
- VFC launched new temperature monitoring resources for VFC providers in 2016:
  - 'Monitoring Storage Unit Temperatures' training on eziz
  - New online storage and handling incident reporting system, 'SHOTS' (Storage and Handling Online Triage System); and
  - Updated and simplified temperature logs and temperature log action guides.



### Temperature Monitoring

- Providers must use current VFC Program temperature logs
- Temperatures must be recorded twice daily, at the beginning and towards the end of each business day
- Vaccine Coordinator must monitor and record the CURRENT, MAX and MIN temperatures in the refrigerator and freezer, date of each reading.
  - If other staff are assigned to monitor and record temperatures, they must complete training on eziz.org and be trained on the use of the devices used by the practice, and how to respond to out-of-range temperatures.

Recording Temperatures



#### Month/Year (Days 1-15) Page Refrigerator Temperature Log Refrigerator Location/ID 4 a. Record CURRENT, MIN, and MAX temperatures.\* Record Time and Take action for one of the b. Circle if TOO WARM or TOO COLD. Refer to ranges. three ranges. CURRENT MAX TOO MAX TOO WARM? 8:00 a.m. 40.5 38.1 43.7 WARM! 33.0 39.2 4:00 p.m NN 37.4 a. Press MEMORY CLEAR/ 54° & warmer RESET buttons. b. Make sure refrigerator door 52° 51° c. Post "Do Not Use Vaccines" 50° 4Q° d. Alert your supervisor. 48° e. Report excursion at MyVFCvaccines.org. 47° OK 46.0° MIN & MAX OK. 45° a. Press MEMORY CLEAR/ 430 RESET buttons.\* p.m. 420 41° 40° Done D.M 300 ОК 38° 37° p.m. 36° 35.0° рлт TOO MIN TOO COLD? COLD! a. Press MEMORY CLEAR/ 34.90 RESET buttons \* 34° b. Make sure refrigerator door 33° 32° c. Post "Do Not Use Vaccines" 31° a.m. 30° d. Alert your supervisor. 29° e. Report excursion at 28° MyVFCvaccines.org. \* For data loggers, check instructions in product guide and at EZIZ.org/assets/docs/IMM-1206.pdf. Review log and sign when completed. Keep logs and excursion reports for 3 years. I certify that temperatures recorded on this log are correct. All temperatures that were TOO WARM or TOO COLD are circled and corrective action was taken. I understand that faisifying logs will result in vaccines being unusable—patients may need to be revaccinated and provider may need to replace vaccines On-site Supervisor's Name & Signature: California Vaccines for Children Program Questions? Call 1-877-243-8832. MyVFCvaccines.org IMM-1125 Page 1 (12/15)

### TOO WARM!

**54**° & warmer

53°

52°

51°

50°

49°

48°

47°

46.10

### **MAX TOO WARM?**

- a. Press MEMORY CLEAR/ RESET buttons.
- b. Make sure refrigerator door is shut.
- c. Post "Do Not Use Vaccines" sign.
- d. Alert your supervisor.
- Report excursion at MyVFCvaccines.org.



### TOO COLD!

34.9°

34°

33°

**32**º

32°

31°

30°

29°

28°

27º & colder

### MIN TOO COLD?

- a. Press MEMORY CLEAR/ RESET buttons.
- b. Make sure refrigerator door is shut.
- c. Post "Do Not Use Vaccines" sign.
- d. Alert your supervisor.
- Report excursion at MyVFCvaccines.org.



F Freezer Temperature Log					Month/Year (Days 1-15) Freezer Location/ID VFC PIN			
	ord the Time r Initials.	and	Check I Alarm trigger	a. nec	de temperature	MIN, and MAX ten	nperatures.* efer to ranges.	Take action for one of the two ranges.
ay of onth	Time 8:00 a.m.	Initials NN	Alarm	CURRENT	₩ MIN -20.2	MAX -9.1	тоо	MAX TOO WARN
imple	4:00 p.m. a.m. p.m.	NN	V	2.4	-9.0	6.2	WARM! 16° & warmer 15° 14°	a. Press MEMORY CLEAR/ RESET buttons.*
2	a.m. p.m. a.m.						13° 12° 11° 10°	b. Make sure freezer door is shut.     c. Post "Do Not Use Vaccines" sign.
4	p.m. a.m.						9° 8° 7°	d. Alert your supervisor. e. Report excursion at MyVFCvaccines.org.
5	p.m. a.m. p.m.						6° 5.1°	
6	a.m. p.m. a.m.						OK 5.0°	
8	p.m. a.m.						4° 3° 2° 1°	MIN & MAX OK.
9	p.m. a.m. p.m.						0° -1° -2°	a. Press MEMORY CLEAR/ RESET buttons.*      b. Make sure freezer door is sh Done.
0	a.m. p.m.						-3° -4° -5°	OK OK
1	a.m. p.m. a.m.						-6° -7°	
3	p.m. a.m.						-9° -10s° -20s°	
4	p.m. a.m. p.m.						-30s° -40 to -58.0°	If temperatures go below -58°F, report excursion at MyVFCvaccines.
5	a.m. p.m.						* For data logge and at <u>EZIZ.or</u>	ers, check instructions in product gu rg/assets/docs/IMM-1206.pdf.
tify ti	hat temperatur	es recorded o	on this log a	are correct. All tem	peratures that wer	e TOO WARM are cir		reports for 3 years.  Ition was taken. I understand that falsifyl
	upervisor's Nan	-	re:					Date:

OK

5.0°

40

**3**°

**2°** 

10

**0**°

-10

-2°

-3°

-4°

-5°

-6°

-**7**°

-8°

-**9**°

-10s°

-20s°

-30s°

-40 to -58.0°

### MIN & MAX OK.

- a. Press MEMORY CLEAR/ RESET buttons.
- **b.** Make sure freezer door is shut. Done.

If temperatures go below -58.0°F, report excursion at MyVFCvaccines.org.

### Temperature Log Review

Supervisors	Review log and sign when completed. Keep logs and excursion reports for 3 years.				
	res recorded on this log are correct. All temperatures that were TOO WARN result in vaccines being unusable—patients may need to be revaccinated a				
On-site Supervisor's Na	me & Signature:	Date:			
Staff Names with Initia	ls:				

California Vaccines for Children Program

Questions? Call 1-877-243-8832. MyVFCvaccines.org

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### Ordering VFC Temperature Logs

#### Home

#### **EZIZ Training**

#### VFC Program

#### Storage & Handling

#### Resources

#### Contact VEC

Phone: 1-877-243-8832 Business hours: 9-5 Fax: 1-877-329-9832

- Find a VFC field representative in your area
- Find other VFC provider offices in your area
- Send us your comments at eziz@cdph.ca.gov

Sign up to receive EZIZ news and VFC letters via emai!





#### Storage & Handling Job Aids

#### Vaccine Management

- Vaccine Management Plan 2016- Word template
- · Role and Responsibilities of the Vaccine Coordinator
- · Monthly Care of Vaccine Storage Units

#### Refrigerator and Freezer Setup

- · Preparing Refrigerators
- · Refrigerator Setup for Vaccine Storage
- Preparing Freezers
- Freezer Setup for Vaccine Storage
- · Safeguard Your Power Supply
- · Do Not Unplug Sign
- · Storage Unit Requirements

#### NEW Monitoring Temperatures

- What's New in 2016?
- Refrigerator Temp Logs: Fahrenheit | Celsius
- Freezer Temp Logs: Fahrenheit | Celsius
- · How to Record Refrigerator and Freezer Temperatures: Fahrenheit | Celsius
- · Reading a Thermometer Display: Fahrenheit | Celsius
- · Data Logger Setup and Use
- · Thermometer Requirements
- · Calibration Requirements
- VFC Vaccine Fact Sheets (view storage temperatures by vaccine)

#### Order printed copies of the 2016 temperature logs for free.

(Available to California VFC providers only)

#### **Related Links**

- Printed copies of many of the materials posted on EZIZ.org can be ordered from your local health department. Check with the immunization program in your area.
- Vaccine Information Statements (VIS)
- Immunization Schedule & Recommendations
- ► Disease Surveillance
- Laws and Regulations
- ► EZIZ Online Training



# TEMPERATURE MONITORING

Thermometers and Digital Data Loggers

### Digital Data Loggers

- A digital data logger (DDL), also known as a "continuous temperature monitoring device" is a thermometer that reads and records temperatures and then stores them in its internal memory.
- Temperatures recorded by a data logger can be viewed on a computer and saved as an electronic or paper file.

#### Importance and Use of Data Loggers

- Information from a digital data logger helps clinic staff:
  - Know the exact times temperatures were out of range.
  - Continuously monitor temperatures even when the clinic is closed. Some data loggers have advanced, remote alert capabilities to notify clinic staff of excursions during non-business hours;
  - Prevent unnecessary vaccine losses when excursion time frames cannot be precisely determined.

### Digital Data Logger Requirements

The following providers are required to use data loggers in 2016:

- All new VFC providers,
- Practices that are open 2 days a week or less, and
- Practices needing to replace their primary or back-up thermometer
- Providers conducting mass vaccination clinics also must use data loggers to monitor temperatures during vaccine transport and at the mass vaccination clinic

All provider will be required to use data loggers starting Jan 1, 2017

### Digital Data Loggers Requirements

- Accuracy of +/-1°F (+/-0.5°C)
- Visual or audible alarm for out-of-range temperatures
- Low battery indicator
- Memory storage of at least 4,000 readings
- Current, minimum, and maximum temperature display
- User-programmable logging interval (or reading rate)
- Certificate of Calibration
- Buffered temperature probe immersed in one of the following: a vial filled with liquid (e.g. glycol, ethanol, glycerin); a vial filled with loose media (e.g. sand, glass beads); or a solid block of material (e.g. Teflon®, aluminum)

### Digital Data Loggers: Use

- Temperatures must be recorded twice daily even if using a digital data logger
- If temperatures are monitored using a continuous temperature device/data logger, download and review of temperature data should occur every two-week period, or at minimum, monthly.

### VFC SHOTS SYSTEM

Storage & Handling Online Triage System

## Storage and Handling Online Triage System

SHOTs will provide guidance on the documentation of out of range temperatures discovered for their vaccine storage unit(s)

SHOTS will provide feedback on whether vaccine manufacturers need to be contacted.

\*\*\*use Internet Explorer

### #MYVFCVACCINES

#### MAIN PAGE

IzzytheBear-PediatricsMD PIN: 888888

Order confirmation email: christina.sapad@cdph.ca.gov Add'l order confirmation email:

christina.sapad@cdph.ca.gov Phone: (510) 100-5555

Address:

850 Marina Bay Pkwy Bldg P

Richmond, CA 94804 **Delivery Information:** 

T, W; TW 9AM TO 12PM AND 1PM TO 6PM

Provider Category: Medium Volume Order Frequency: Every 2 months

<u>Update Practice Information »</u> Logout Provider of Record: Christina Sapad

Provider of Record email: christina.sapad@cdph.ca.gov

Vaccine Coordinator: Christina Sapad

Vaccine Coordinator email: christina.sapad@cdph.ca.gov



#### **Vaccine Storage Excursion Report**

OCurrently do not have MMR.



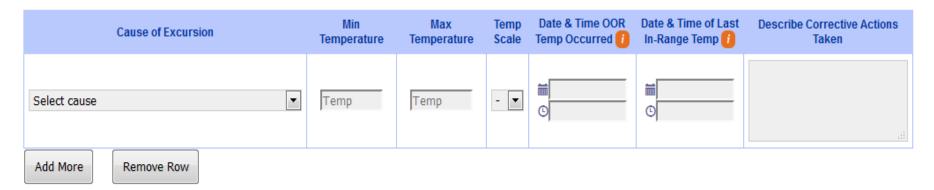
Equipment Do not use the affected vaccines or return the affected vaccines until you have received further instructions at the end of this report. Please provide the following information regarding your Vaccine Storage excursion. Note: All fields are required. 1.) Name of person reporting: 2.) How was temperature excursion discovered? O Discovered by provider staff (Reporting) O Discovered by the VFC Program (Reporting) 3.) Date and time of discovery: 4.) Please confirm the storage unit(s) involved in this excursion: Refrigerator: General Electric - Location: Wall ☐ Freezer: Toshiba - Location: Wall 1, #258686 Refrigerator: General Electric - Location: Wall.e. ☐ Freezer: Absocold - Location: Wall 1-b, #285687 ☐ Other, not listed: 5.) Were any of the vaccines affected in this storage excursion involved in a previous temperature excursion? Oyes O No 6.) Where is MMR stored? O Refrigerator O Freezer

#### Enter temperatures and times.

Include any information for the same units that were not previously reported.

#### Refrigerator: Kenmore - Location: front

Instructions: Use this table to document the out-of-range (OOR) temperatures and actions taken. The system will calculate total time out of range. Only enter excursions not previously reported.



#### Refrigerator: Kenmore - Location: Room B

Instructions: Use this table to document the out-of-range (OOR) temperatures, actions taken, and the total time temperatures went outside of the recommended storage range based on your data logger report. Only enter excursions not previously reported.

Cause of Excursion	Min Temperature	Max Temperature	Temp Scale	Date & Time OOR Temp Occurred	Total Time Out of Range	Describe Corrective Actions Taken
Select cause	Temp	Temp	- 🔻	<u></u>	Time	.dl
Add More Remove Row						

### **Vaccine Storage Excursion Report**



#### Call vaccine manufacturers & provide the details below.

- · Only licensed health care staff ... should contact vaccine manufacturers.
- · Print this page to use as a reference.
- · Request a letter containing stability information and enter the results below.
- · Your account will be put on hold until this report is completed.

#### Print

After obtaining stability information, enter required vaccine viability determination, date of call, and case numbers given by the manufacturers (NOTE: Some manufacturers do not provide Case Number. Please obtain Name of Person Contacted).

#### General Electric Wall

Highest Temperature 50.01 °F, Total # of hours too warm: 00:00:00

Manufacturer	Vaccine	Result	Date Called	Case # OR Contact Person
Sanofi Pasteur 800-822-2463	Daptacel	O OK to Use O Do NOT Use		<u>^</u>

Back

Next

(Please ensure that the information inputted is correct before proceeding.)

#### Vaccine Storage Excursion Report for PIN 888888



This report will triage your temperature excursion. The information you submit will determine if vaccines can be used or if vaccine manufacturers need to be contacted.

Do not use or return vaccines until instructed to at the end of this report.

Start

**View Temperature Excursion History** 

#### Re-opened Reports

		Pending Reports
11/25/2015	116: General Electric	Finish & Submit
11/25/2015	115: General Electric, test	Finish & Submit
11/25/2015	114: test, General Electric	Finish & Submit

		Completed Reports	
11/25/2015	117: General Electric		View

### VACCINE MANAGEMENT

### VFC Eligibility

The VFC Programs was created to meet the vaccination needs of children from birth through 18 years of age.

### MHO'S ELIGIBLE





Children eligible to receive VFC provided vaccines are:

MEDICAID (MEDI-CAL)

CHILD HEALTH &

DISABILITY PREVENTION

(CHDP) PROGRAM

No HEALTH INSURANCE\*

UNDER-INSURED\*\*

AMERICAN INDIAN

ALASKAN NATIVE

### Vaccine Management Plans

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### Acknowledgement & Signature Log

#### SIGNATURE LOG

Each year sign and date one signature block and when you up update practice-specific information. By signing, staff acknowledges they have reviewed and are familiar with all the information in the document.

Updates & Comments		
Provider of Record	Signature/Date	
Vaccine Coordinator	Signature/Date	
Backup Vaccine Coordinator	Signature/Date	
Provider of Record Designee	Signature/Date	
Additional Staff	Signature/Date	

Updates & Comments		
Provider of Record	Signature/Date	
Vaccine Coordinator	Signature/Date	
Backup Vaccine Coordinator	Signature/Date	
Provider of Record Designee	Signature/Date	
Additional Staff	Signature/Date	

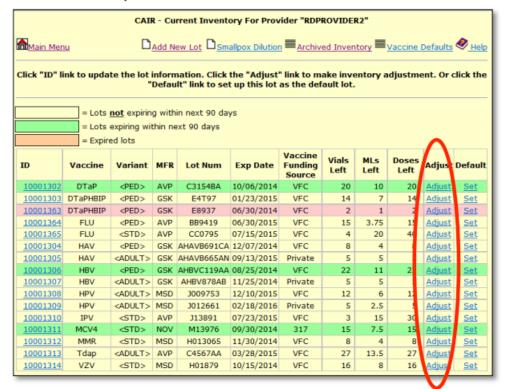
Updates & Comments		
Provider of Record	Signature/Date	
Vaccine Coordinator	Signature/Date	
Backup Vaccine Coordinator	Signature/Date	

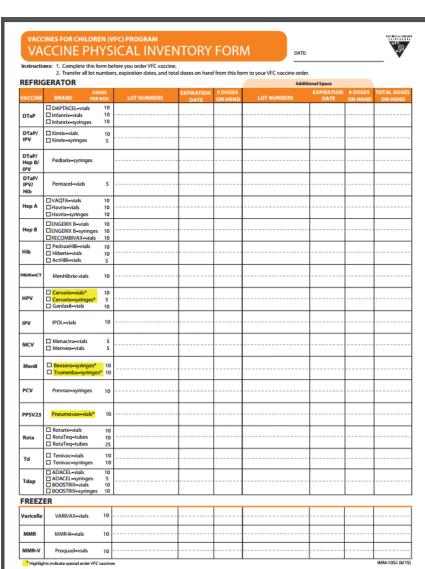
### **VFC Vaccine Ordering**

- Trained and authorized clinic staff must submit vaccine orders through the practice's account on MyVFCvaccines.org.
- Place orders according to the practice's VFC-assigned ordering category (very high, high, medium, or low volume) and frequency (monthly, bimonthly, or quarterly).
- Provide all necessary inventory and usage information.

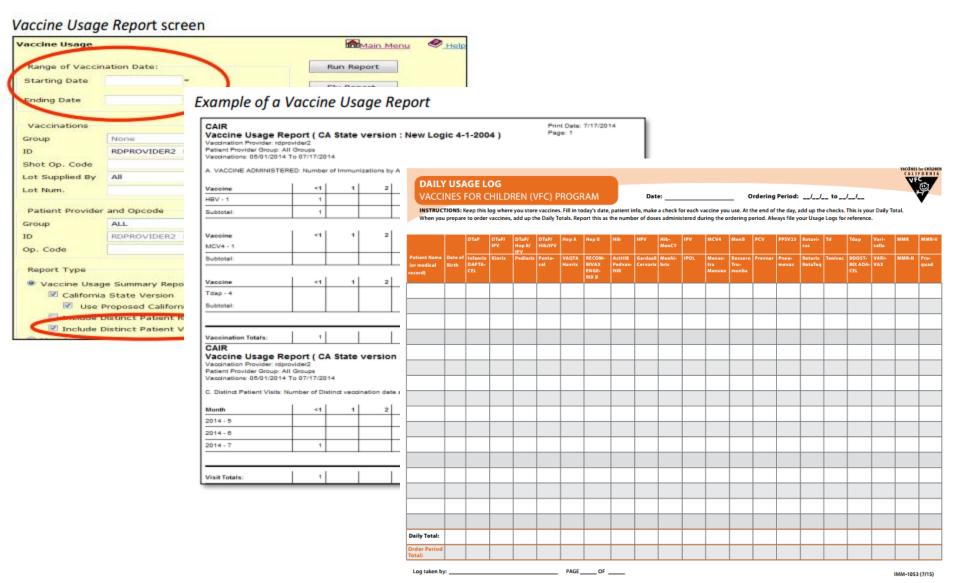
### VFC Vaccine Usage: Inventory

#### Current Inventory screen





### VFC Vaccine Ordering: Vaccine Usage



### **VFC Vaccine Ordering**

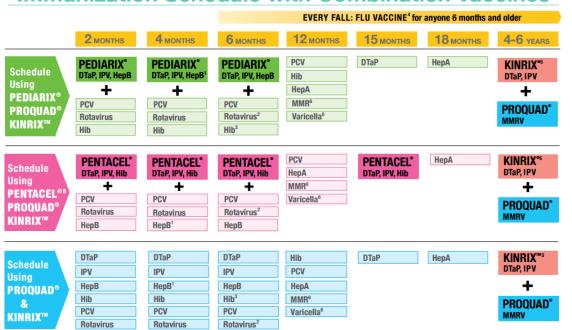
- The VFC Program encourages providers to choose one formulation when multiple vaccine products are available to avoid inadvertent administration errors.
- Alert the VFC Program of any temporary closures, including vacation and building management issues, which might affect deliveries.
- Vaccine doses not accounted for or lost due to negligence may be replaced dose for dose by practice

### Vaccine Ordering

VFC Vaccines	VFC Doses Administered Enter -0- for no doses	VFC Vaccine Inventory (Doses On Hand) Enter -0- for no doses	New VFC Vaccine Order
DTaP	VFC	# of Doses   Lot Number   Expiration (mm/dd/yyyy) Add More	Choose vaccine   Add More
DTaP/IPV	VFC	# of Doses   Lot Number   Expiration (mm/dd/yyyy) Add More	Choose vaccine    Add More ↓
DTaP/Hepatitis B/IPV	VFC	1Choose vaccine # of Doses   Lot Number   Expiration (mm/dd/yyyy) Add More	Pediarix Single dose syringes - 10 per box
DTaP/IPV/Hib	VFC	# of Doses   Lot Number   Expiration (mm/dd/yyyy) Add More	Pentacel Single dose vials - 5 per box
Hepatitis A	VFC	# of Doses   Lot Number   Expiration (mm/dd/yyyy)  Add More	Choose vaccine   Add More

### Vaccine Ordering: Choice

- Providers should review the specific age indications and recommended dosing schedule for all vaccines.
- For example, some vaccines are 2 doses and some vaccines are 3 doses that protect against the same diseases.
- Once the clinic determines which schedule and vaccines will be used to accommodate ALL staff should be informed and educated on the new vaccines and schedule.
   Immunization Schedule with Combination Vaccines



### Vaccine Inventories

- Clearly label and separate VFC-supplied and private vaccine. When possible, store the vaccines on different shelves in the storage unit.
- Borrowing between VFCsupplied and private stock is prohibited.
- Maintain inventory and invoices and make them available upon request





\*\*317 vaccine is for local health departments only



### **VFC Vaccine Ordering**



### **VFC Online Ordering**

#### Additional Resources

- http://eziz.org/assets/docs/IMM-1055.pdf
- http://eziz.org/faq/vaccine-ordering/
- http://eziz.org/vfc/online-ordering-tutorial-video/

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